

REMARKS/ARGUMENTS

Status of Claims

Claims 1 and 14 have been amended.

Claims 9-10 are withdrawn.

Claims 15-17 and 34-52 were previously canceled.

Claim 54 is currently canceled.

Thus, claims 1-14, 18-33 and 53 are currently pending in this application.

Applicants hereby request further examination and reconsideration of the presently claimed application.

Examiner Interview

Applicants thank the Examiner for the courtesy of a telephonic interview on May 19, 2011, the content of which is accurately reflected in the May 23, 2011 interview summary.

Claim Rejections – 35 U.S.C. § 103

Claims 1-8, 11-22, 25-32, 53 and 54 stand rejected under 35 U.S.C. § 103(as) as being unpatentable over Katdare, et al., WO 95/29679 (hereinafter “*Katdare*”) in view of Adamski, et al., WO 01/85176 (hereinafter “*Adamski*”).

Claims 23, 24 and 33 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Katdare* and *Adamski* in further view of Flash-Ner-Barak, et al., WO 2002/00204 (hereinafter “*Flash-Ner-Barak*”).

Claim 54 has been canceled. Claims 1-8, 11-13, 15-33 and 53 depend from claim 1. Thus, the pending claims stand or fall on application of the cited references to independent claims 1 and 14.

The Legal Standard for Obviousness

The MPEP provides:

The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit.

See MPEP § 2143. In *KSR Int'l Co. v. Teleflex, Inc.*, the United States Supreme Court also noted that, “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art,” but, additionally whether “the claim extends to what is obvious.” *See KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1741-42 (2007). Expounding on its edict, the Supreme Court went on to opine that an obviousness determination is based upon a “proper application of *Graham*,” including consideration of “secondary factors” that may weigh against an obviousness determination. *See KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. at 1745 (citing *Graham v. John Deere Co. of Kansas City, et al.*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966)). The “proper application of *Graham*” begins with a determination of whether the cited prior art contains all the elements of the contested claims. *See Graham v. John Deere Co. of Kansas City*, 383 U.S. at 22 (an obviousness determination begins with a finding that “the prior art as a whole in one form or another contains all” the elements of the claimed invention).

Applicants submit that with regard to the pending claims, a *prima facie* case of obviousness cannot be established as the cited references do not contain all the elements of the pending claims. Applicants have amended claim 1 to incorporate the limitations of now canceled claim 54 and recite:

An oral formulation which includes an intragranular phase comprising a bisphosphonic acid derivative, at least one carbohydrate alcohol **and at least one diluent, the diluent being additional to**

the carbohydrate alcohol, together with an aqueous binder,
wherein the amount of the carbohydrate alcohol is from 15 to 40
wt.% of the weight of the formulation.

See *supra*, emphasis added. Claim 14 has been similarly amended. The Office Action relies on the combination of *Katdare* and *Adamski* to teach the instantly claimed limitation *wherein the amount of the carbohydrate alcohol is from 15 to 40 wt.% of the weight of the formulation*. Specifically, the Office Action states:

Based on the combined teachings of the applied prior art, the amount of a particular diluent present in pharmaceutical compositions of bisphosphonates such as alendronic acid range from 30% to 80% by weight of the composition.

Further, the Office Action relies on *Katdare* to teach the instantly claimed limitation *at least one diluent, the diluent being additional to the carbohydrate alcohol*. Applicants respectfully submit that while *Katdare* and *Adamski* both disclose the use of a formulation that may comprise more than one diluent; only *Adamski* discloses the use of a specific amount of carbohydrate alcohol. Consequently, assuming the Office Action were correct and the range of diluents in general encompassed by the combination of *Katdare* and *Adamski* were 30% to 80% (*arguendo*); the combination does not disclose a range of carbohydrate alcohol as instantly claimed (i.e., *wherein the amount of the carbohydrate alcohol is from 15 to 40 wt.% of the weight of the formulation*). To the contrary, the only reference that provides a range for the amount of carbohydrate alcohol is *Adamski* who discloses the use of mannitol in the range of 50-80% which is outside of the 15-40 wt.% instantly claimed. The Office Action remarks that despite there being no disclosure of the instantly claimed limitation *wherein the amount of the carbohydrate alcohol is from 15 to 40 wt.% of the weight of the formulation*:

Lower amounts of the diluent mannitol can be used when a second diluent, such as microcrystalline cellulose is also present in the composition.

See Office Action at 4. Applicants respectfully submit this remark is merely conclusory and the Office Action's suggestion that the ordinarily skilled artisan *may* use lower amounts of mannitol in the presence of a second diluent does not necessarily place that "lower amount" within the instantly claimed range of *from 15 to 40 wt.% of the weight of the formulation*.

Further, the Office Action's suggestion is refuted by the disclosure of *Adamski*. *Adamski* discloses compositions having a second diluent. See *Adamski*, page 10, Tablet formulation. Notably, the amount of mannitol in the tablet formulation in the presence of additional diluents is 79.125%. Thus, contrary to the Office Action's suggestions, *Adamski* does not reduce the amount of mannitol in the presence of additional diluents; rather the amount of mannitol used in the presence of additional diluents remains near the maximum of the range disclosed by *Adamski* (i.e., 50-80 wt.%).

Applicants submit that one of ordinary skill in the art when given the benefits of the teachings of *Katdare* and *Adamski* would find that (1) only *Adamski* recites a specific range for the amount of a carbohydrate alcohol; (2) the range recited for the carbohydrate alcohol is from 50-80 wt%; (3) the advantageous properties of the compositions (e.g. stability, uniformity) are attributed to the presence of a carbohydrate alcohol; and (4) the amount of the carbohydrate alcohol remains within the disclosed range of 50-80 wt.% in the presence of one or more additional diluents. Given the totality of the evidence, the ordinarily skilled artisan would have no motivation to modify the references and would instead be lead away from the Applicant's instantly claimed limitation *wherein the amount of the carbohydrate alcohol is from 15 to 40 wt.% of the weight of the formulation*.

Applicants submit that the combination of *Katdare* and *Adamski* fail to disclose the instantly claimed limitation *wherein the amount of the carbohydrate alcohol is from 15 to 40*

wt.% of the weight of the formulation. Absent such disclosure, there exists and evidentiary gap that is fatal to a *prima facie* case of obviousness. Applicants respectfully request withdrawal of the rejections and allowance of the pending claims.

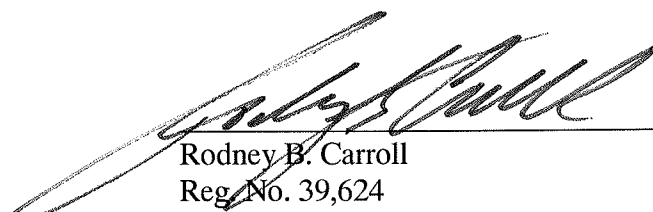
CONCLUSION

Consideration of the foregoing amendments and remarks, reconsideration of the application, and withdrawal of the rejections are respectfully requested by Applicants. No new matter is introduced by way of the amendment. It is believed that each ground of rejection raised in the Final Office Action dated April 8, 2011 has been fully addressed. If any fee is due as a result of the filing of this paper, please appropriately charge such fee to Deposit Account Number 50-1515 of Conley Rose, P.C., Texas. If a petition for extension of time is necessary in order for this paper to be deemed timely filed, please consider this a petition therefore.

If a telephone conference would facilitate the resolution of any issue or expedite the prosecution of the application, the Examiner is invited to telephone the undersigned at the telephone number given below.

Respectfully submitted,
CONLEY ROSE, P.C.

Date: 6-1-11



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